K070028

# Attachment 4

## *510 (k) Summary*

**Submitter's Identification**

FEB 8 2007

Actherm Inc.
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Taiwan
Tel: +886 3 553 7315
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Contact Person: Richard Hsieh

Date prepared: December 25, 2006

**Name of the devices**

**Classic/Hypothermia Digital Clinical Thermometer,** Model ACT2000/ACT2000+, ACT2010/ACT2010+, ACT2020/ACT2020+, ACT2030/ACT2030+, ACT2130/ACT2130+, ACT2038/ACT2038+;

**Flexible Digital Clinical Thermometer**, Model ACT3020/ACT3020+, ACT3030/ACT3030+, ACT3136/ACT3136+, ACT3020 Express, ACT3020 Express, ACT3030 Express, ACT3136 Express, ACT3230 Express;

**10-Second Digital Clinical Thermometer**, Model ACT2010 Express, ACT2020 Express, ACT2030 Express, ACT2130 Express, ACT2230 Express, ACT2330 Express;

**Left-Right Handed Digital Clinical Thermometer**, Model ACT2030 LR/ACT2030+ LR, ACT2130 LR/ACT2130+ LR, ACT2230 Express LR, ACT3230 Express LR, ACT3136 Express LR;

**Basal Digital Clinical Thermometer**, Model ACT2010 Basal, ACT2010 Express Basal, ACT3020 Basal, ACT3020 Express Basal, ACT3230 Basal, ACT3136 Basal, ACT2130 Basal, ACT3136 Express Basal, ACT6070 Basal;

**Lightweight-Probe Digital Clinical Thermometer**, Model ACT6070 Express;

**Classification Name**

*Clinical Electronic Thermometer*
(21 CFR 880.2910 Product Code FLL)

**Predicate Device Information**

| | |
|---|---|
| Actherm Digital Clinical Thermometer, Model ACT2000, ACT2020 et al. | (K010238) |
| Digital Clinical Thermometer, Model ACT2030, ACT2038 | (K021612) |
| Digital Clinical Thermometer, Model ACT3020 | (K021614) |
| Digital Clinical Thermometer, Model ACT2130, ACT3136 et al. | (K031905) |
| Lumiscope Model 2018 Thermometer | (K954792) |

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## evice Description

The ***Classic/Hypothermia Digital Clinical*** *Thermometer* consists of an electronically sensor which is located in a metal probe and is connected with a PCB and a Liquid Crystal Display all situated in a pen-like plastic housing. This structure is used for all kind of Thermometer mentioned in this description.
*Hypothermia Thermometer* have a greater measuring range so that they can be used as device for under cooled person temperature monitoring.
A flexible probe tip is provided by the ***Flexible Digital Clinical Thermometer*** that makes the measuring of the temperature more comfortable and safer.
With the patented ***10-Second Digital Clinical Thermometer*** every user is able to receive the result of the measurement in a very quick time. The Express Models also operates with the same efficient reliability and accuracy like the other Thermometer.
Due to a special integrated sensor in the ***Left-Right Handed Digital Clinical Thermometer*** display can easily be read whether the Thermometer is held in the right or the left hand. Especially for left-handed people it makes the measuring result read off more pleasant.
The ***Basal Digital Clinical Thermometer*** have a fourth digit on the display, because the measurement of this Thermometer is even more accurate compared with normal Thermometer. This precisely measuring method can be used to monitor and interpreting basal temperature changes.
The ***Lightweight-Probe Digital Clinical Thermometer*** consists of a flexible probe, connection cord and a display unit embedded in a round housing.

Variants Descriptions: "+" or Hypothermia, Express, Dual scale, Backlight, LR, following with the model numbers indicates different measuring range, different measuring time, scale switchable, with backlight with Left-Right Handed function.

For all Thermometers is essential, that they consist of a temperature sensor embedded in a special designed metal probe, which could be flexible or inelastic. This sensor is connected with the IC unit, which is connected with a Liquid Crystal Display (LCD) to display the measured temperature. All parts are situated in a pen-like plastic housing. During measuring, only the maximum measured value is displayed on LCD window and all devices are non-predictive.

All variant thermometers comply with referenced product standards of ATSM E1112-00, EN12470-3, IEC 60601-1, IEC 60601-1-2 and ISO 10993-1.

## Intended Use

For all variant Thermometers the intended use is as medical device supplied by internal power and intended to precisely measure human body temperature. It can be used in the measurement of oral, axillary and rectal temperature. They are used alone for human beings at all ages, especially professional medical practitioners, to diagnosis or observe human states of health. All kinds of Actherm Digital Clinical Thermometer help to detect and to make accurate judgements of states of health, protect user safety and public health.

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**Comparison to Predicate Devices**

The ***Classic/Hypothermia, Flexible, 10-Second, Left-Right Handed and the Basal Digital Clinical Thermometer*** are substantial equivalent to the Predicate Devices Actherm Digital Clinical Thermometer. All new devices use the same kind of technology and have the same design as the predicate devices. (Exception is Model ACT3230 Express which has a new, slightly changed design.) All devices are only supported by a new Model feature in comparison to the predicate devices to increase the device performances. I.e. the Basal Digital Thermometer has a higher accuracy. The material, chemical composition and the energy source remains the same as the used Predicate Devices.
The ***Lightweight-Probe Digital Clinical Thermometer*** is substantial equivalent to the Predicate Device Lumiscope Model 2018 Thermometer (K954792). Only the design and the used technology are adapted to the Actherm Inc. corporate policy. The material and the chemical composition remains the same as the used Predicate Devices.

**Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence is as follows:**

Compliance to applicable voluntary standards includes ASTM E1112-00, EN 12470-3 as well as IEC 60601-1, IEC 606001-1-2 and ISO 10993-1 requirements.

Guidance Documents included the "FDA Guidance on the Content of the Premarket Notification 510 (k) Submissions for Clinical Electronic Thermometers".

**Conclusion**

The **Classic/*Hypothermia Digital Clinical Thermometer, Flexible Digital Clinical Thermometer, 10-Second Digital Clinical Thermometer, Left-Right Handed Digital Clinical Thermometer, Basal Digital Clinical Thermometer*** and the ***Lightweight-Probe Digital Clinical Thermometer*** with all corresponding Models have the same intended use and similar technological characteristics as the cleared devices of Actherm Inc. Digital Clinical Thermometer. Moreover, verification and validation tests contained in this submission clearly demonstrate that any differences in their characteristics do not raise any new questions of safety or effectiveness. Furthermore, those engineering differences do not affect the intended use or alter the fundamental scientific technology of the cleared devices of Actherm Inc. Digital Clinical Thermometer.
Thus, the ***Classic/Hypothermia Digital Clinical Thermometer, Flexible Digital Clinical Thermometer, 10-Second Digital Clinical Thermometer, Left-Right Handed Digital Clinical Thermometer, Basal Digital Clinical Thermometer,*** and the ***Lightweight-Probe Digital Clinical Thermometer*** with all corresponding Models are substantially equivalent to the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Jubei, HsinChu 302
TAIWAN

FEB 8 2007

Re: K070028
Trade/Device Name: Classic/Hypothermia Digital Clinical Thermometer; Flexible Digital Clinical Thermometer; 10-Second Digital Clinical Thermometer; Left Right Handed Digital Clinical Thermometer; Basal Digital Clinical Thermometer; Lightweight-Probe Digital Clinical Thermometer
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 1, 2007
Received: February 5, 2007

Dear Mr. Hsieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

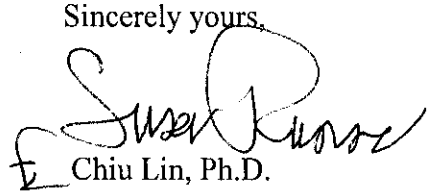
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Attachment 2

*Indications for Use Statement*

**510 (k) Number** (if known)

K070028

**Device Name**

**Classic/Hypothermia Digital Clinical Thermometer,**

**Flexible Digital Clinical Thermometer,**

**10-Second Digital Clinical Thermometer,**

**Left-Right Handed Digital Clinical Thermometer,,**

**Basal Digital Clinical Thermometer,,**

**Lightweight-Probe Digital Clinical Thermometer;**

**Indications for Use**

All **Digital Clinical Thermometers** are intended to precisely measure human body temperature. The Thermometers can be used in the measurement of oral, axillary and rectal temperature.

Prescription Use _____ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use ___X___ (Per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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